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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,477	12/11/2001	Masahiro Imoto	1830/50521	4095

23911 7590 06/28/2005  
CROWELL & MORING LLP  
INTELLECTUAL PROPERTY GROUP  
P.O. BOX 14300  
WASHINGTON, DC 20044-4300

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,477	IMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 35,36 and 41-59 ☒ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 is/~~are~~ allowed.
- 6) ☒ Claim(s) 35 and 41-59 ☒ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This office action is in response to the amendment filed on April 13, 2005.

Claims 35-36 and 41-59 are pending in this application.

#### ***Election/Restriction***

As indicated in the previous office action, the search and examination of the application was based on the elected species of Compound No. 2. Applicant's amendment dated April 13, 2005 overcame the rejections of the previous office action. As per the guidelines of MPEP § 803.02, the search was expanded to the genus of formula (I) of the instantly amended claims and art was found.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

***The following rejections are necessitated by the amendment and/or under new grounds:***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 35 and 41-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 35, the definition of A<sup>1</sup> and A<sup>2</sup> includes the recitation "an **optionally** substituted alkyl group, selected from the group consisting of methyl, ethyl, ....., and tert-butyl, wherein the alkyl group is ~~optionally~~ substituted by phenyl, .....,". This recitation is confusing because it is not clear whether the alkyl group is **optionally** substituted (which includes unsubstituted alkyl) or is it always substituted by one of the groups recited therein (i.e., phenyl, 5-pyrimidyl, etc.). Since the second occurrence of the term 'optionally' is deleted, it appears that applicant intends -- a substituted alkyl --. Appropriate amendment or clarification is required.
2. Claim 59 recites the limitation "2-(3-aminophenyl)-1,4,5,6-tetrahydropyrimidine" in line 5 (page 8, line 4). There is insufficient antecedent basis for this limitation in claim 35 on which claim 59 is dependent. As per claim 35, the definition of A<sup>2</sup> does not include 'a substituted phenyl'.
3. Claim 59 recites the limitation "2-(2-chloro-5-thiazolyl)-1,4,5,6-tetrahydropyrimidine" in line 7 (page 8, line 4). There is insufficient antecedent basis for this limitation in claim 35 on which claim 59 is dependent. As per claim 35, the substituted heterocyclic group in the definition of A<sup>2</sup> does not include 'thiazolyl'.
4. Claim 59 recites the limitations "1-(3-pyridazinyl)methyl-1,4,5,6-tetrahydropyrimidine; 1-(2-chloro-5-thiazolyl)methyl-1,4,5,6-tetrahydropyrimidine; 2-(2-chloro-5-thiazolyl)methyl-1,4,5,6-tetrahydropyrimidine" in lines 12-14 (page 8, lines 9-11). There

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is insufficient antecedent basis for this limitation in claim 35 on which claim 59 is dependent. As per claim 35, the definition of A<sup>1</sup> and A<sup>2</sup> does not include a methyl substituted by 3-pyridazinyl or 2-chloro-5-thiazolyl.

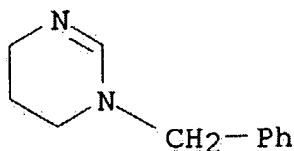
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

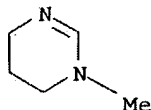
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 130:338236 (1999). The instant claims read on reference disclosed compound, see the compound having RN 1602-94-4 (depicted below for convenience):



The reference compound represents the instantly claimed compound of formula (I) wherein A<sup>2</sup> is H and A<sup>1</sup> is methyl substituted by phenyl.

Applicant's attention is directed to compound of RN 2304-03-2 in the abstract (depicted below):



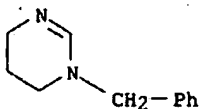
which also represents a compound of formula (I) wherein A<sup>1</sup> is methyl and A<sup>2</sup> is H (if unsubstituted alkyl is intended for A<sup>1</sup> or A<sup>2</sup>).

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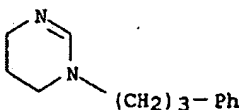
2. Claims 35, 41, 46-49 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 952802. The instant claims read on reference disclosed compounds, see the formula on page 1 and the specific compounds disclosed in the examples.

3. Claims 35, 41, 46-49 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Brimblecombe et al., CAPLUS Abstract 70:41409 (1970). The instant claims read on reference disclosed compounds, see the compounds disclosed in the reference (some of the representative compounds depicted below for convenience):

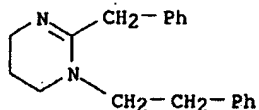
RN 1602-94-4 CAPLUS  
CN Pyrimidine, 1,4,5,6-tetrahydro-1-(phenylmethyl)- (9CI) (CA INDEX NAME)



RN 25099-92-7 CAPLUS  
CN Pyrimidine, 1,4,5,6-tetrahydro-1-(3-phenylpropyl)- (8CI, 9CI) (CA INDEX NAME)



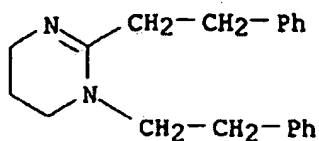
RN 26148-96-9 CAPLUS  
CN Pyrimidine, 2-benzyl-1,4,5,6-tetrahydro-1-phenethyl-, hydrochloride (8CI)  
(CA INDEX NAME)



●x HCl

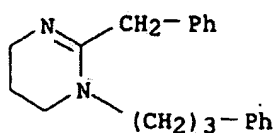
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RN 26148-97-0 CAPLUS  
CN Pyrimidine, 1,4,5,6-tetrahydro-1,2-diphenethyl-, hydrochloride (8CI) (CA INDEX NAME)



● x HCl

RN 26149-00-8 CAPLUS  
CN Pyrimidine, 1,4,5,6-tetrahydro-2-(phenylmethyl)-1-(3-phenylpropyl)-, monohydrochloride (9CI) (CA INDEX NAME)

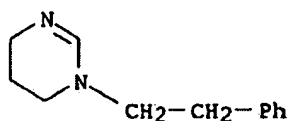


● HCl

RN 27994-54-3 CAPLUS  
CN Pyrimidine, 1,4,5,6-tetrahydro-1-phenethyl-, monomethiodide (8CI) (CA INDEX NAME)

CM 1

CRN 25099-81-4  
CMF C12 H16 N2



CM 2

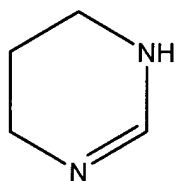
CRN 74-88-4  
CMF C H3 I

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4. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Magosch, DE 2154948 (1973). The instant claims read on reference disclosed compounds, see the formula on page 2, and the species of Examples 3-9.

Note: The definition provided for A<sup>1</sup> and A<sup>2</sup> in the instant claims includes 'an optionally substituted alkyl group' and therefore includes unsubstituted alkyl groups as well.

5. Claims 35, 41, 46-49 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 19834816 (published February 3, 2000). The instant claims read on reference disclosed compound, see the formula Ia or Ib wherein R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are H.



1,4,5,6-tetrahydropyrimidine

6. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Aspinall, CAPLUS Abstract 34:43299 (1940). The instant claim reads on reference disclosed compound, see RN 1606-49-1. The instant claim recites that A<sup>1</sup> and A<sup>2</sup> are each a hydrogen atom and therefore, the claim reads on reference compound.

***Allowable Subject Matter***

Claim 36 is allowed. The references of record do not teach or fairly suggest the claimed compounds.



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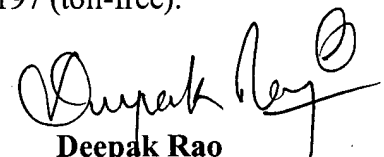
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

June 24, 2005